patients expire. **METHODS:** Retrospective chart review of 105 home hospice patients with a narcotic waste destruction record who expired during a 3-month period in 2007 while receiving care from 4 small hospices (average daily census [ADC] <60) and 1 large (ADC = 160) hospice in the Southeastern Pennsylvania region. Data were collected through review of narcotic waste destruction records as recorded by nurses at the time of patient death. Strength of formulation was recorded sporadically. Hospice nurses were surveyed about CS disposal methods. **RESULTS:** Mean age of the patients was 78, (range 44–103); majority (57%) was diagnosed with cancer, followed by heart failure (24%). Average length of stay in hospice was 42 days (median 21). Almost all patients had unused CS; morphine concentrate (20 mg/ml) was the most common medication (average 31.8 ml./patient). Collectively, over 3 liters (64,680 mg) of morphine were destroyed. Lorazepam was the next most common drug with 990 tablets and 397 ml liquid wasted. Other CS remaining at the time of death included varying strengths of long-acting morphine (251 tablets); OxyContin (90 tablets); and unused transdermal fentanyl (57 patches). Hospice nurses disposed of all unused CS by flushing them down the toilet. **CONCLUSION:** Although not excessive on an individual level, the amount of CS waste in hospice is significant when viewed in the aggregate. When flushed, these medications reach water ways, potentially posing environmental or health hazards. Regulatory changes are required to address disposal of unused CS. Future analyses should examine the cost of CS medication waste in hospice.

PHP14

ESTIMATION OF USAGE OF NEW DRUG AFTER REIMBURSEMENT FOR BUDGET IMPACT ANALYSIS

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OBJECTIVE: The estimation of budget impact is important in listing a new drug, but there are a lot of uncertainties. We analyzed usage of new drug after reimbursement and investigated various factors influencing budget impacts of the new drug to get a guidance for public insurance BIA in Korea. **METHODS:** We used 3 year claims data of 23 new drugs listed in 2004 to analyze usage pattern and market share. We evaluated influencing factors that clinical improvements, treatment cost, disease burden, patient number, market competition, type of company, etc. and conducted multiple regression analysis using these factors. **RESULTS:** The indications of the 23 listing drugs were for cancer, hypercholesterolemia, diabetes, schizophrenia, pneumonia, peptic ulcer, rheumatoid arthritis, hepatitis B, HIV treatment, etc. At third year after new drug listing, average market share incrementally rose to 20% (0.06–78%, range) both in patient number and volume of use. In case of the new drug with clinical improve and higher cost, the average market share amounted to 33% (n = 4). The market share of drugs with no improve and lower costs amounted to 26% (n = 8). When total patient number of new and pre-listed drugs were under 50,000, market share of new drugs amounted to 25%, 35% of total volume and patient number, respectively. But in case of over 250,000 of patients, market share of new drugs were less than 10% in both. New drugs commanded 27%, 4%, 0.08% of market when number of pre-listed competing drugs were <25, 5–25, 25<, respectively. When the company is domestic, new drugs amounted to about 4% of market share and 25% when it is not. **CONCLUSION:** Clinical improvements, disease burden, number of patients, number of pre-listed drug, and company type may affect to market diffusion of new drugs. So we suggest these results be considered in forecasting future usage of new drug and conducting budget impact analysis.

PHP15

EVALUATING THE USE OF PROVISIONAL PATENTS BY THE PHARMACEUTICAL INDUSTRY: THE EXPERIENCE OF THE UNITED STATES

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OBJECTIVE: The U.S. intellectual property regulations allow for claiming the right of priority by an inventor by filing a patent in a foreign country or by filing a U.S. provisional patent. The study evaluated the provisional patent system introduced in 1994 by the Uruguay Round Agreement Act (URAA). **METHODS:** Data on patents listed in the FDA Orange Book (OB) for new chemical entities approved between 1980 and 2007 were derived from the USPTO. Descriptive statistics were calculated for the variables included in the study. Chi-square and t-tests were used to assess differences between groups. **RESULTS:** The OB listed 1452 patents, of which 9.6% claimed priority from a U.S. provisional patent and 39.5% claimed priority from a foreign priority filing. The mean time gained was 328.9 ± 75.2 days from provisional patents and 340.8 ± 60.3 days from foreign rights of priority. The proportion of U.S. companies that obtained a foreign or provisional right of priority increased from 27.4% prior to 1995 to 75.2% after 1995 ($p < 0.001$). This increase was due to the use of provisional patents. A significant increase in the use of provisional patents and a significant decrease in the use of foreign right of priority also occurred in non-US companies, nevertheless, no increase in the combined use of a foreign and provisional right of priority was found for non-US companies. **CONCLUSION:** The foreign companies significantly decreased the use of foreign priority patents while increasing the use of provisional patents. The introduction of provisional patents to the existing foreign priority system resulted in a three-fold increase in the use of these systems by U.S. companies. The 1995 URAA change in the USPTO priority system has significantly influenced the frequency by which U.S. companies seek a foreign or a provisional right of priority.

PHP16

IMPROVING HEALTH TECHNOLOGY APPRAISAL AND DECISION-MAKING: WHAT HAS THE BRITISH PARLIAMENT'S INQUIRY OF NICE TAUGHT US?

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OBJECTIVE: The British Parliament recently held an inquiry into the National Institute for Health and Clinical Excellence (NICE) health technology appraisal (HTA) process. We summarized stakeholder concerns about health economic and decision methodology used for HTAs appraisals and funding decisions, particularly with regard to serious/life-threatening illnesses, and drew comparisons to standards among other nations that use HTA to understand why criticisms might have arisen. **METHODS:** A systematic review was conducted of written evidence submitted to Parliament about the appraisal process and corresponding health economic methods. Stakeholders were limited to manufacturers, professional and trade associations, and patient/disease advocacy organizations (limited to oncology). We excluded evidence from individuals. We extracted themes from this evidence and generated items for a comparison of methods of other countries that conduct appraisals. Only publicly available, English-language qualitative data were considered. **RESULTS:** We identified written evidence from 92

constituents through August 1, 2007, of which evidence from 27 were extracted using our criteria. Stakeholder comments on the HTA process and decision methodology were distilled into 12 categories, ranging from impact of severity/rarity of disease on acceptability of cost-effectiveness thresholds to over-reliance of QALYs in decision-making. Compared to attributes reported for other countries, NICE's criteria and methods for health economic assessment and decision-making varied substantially, such as that of the model perspective, e.g., payer versus societal. **CONCLUSION:** We found that aspects of NICE technology appraisals garner criticism common to many stakeholders. This underscores the need to reconsider how current health economic and decision methodology might be improved. Furthermore, country-level heterogeneity in HTA processes and methods suggests the need to determine why these variations arise, and whether they reflect societal preferences or misunderstandings of appropriate methods.

PHP17

HOW MANDATORY PRICE REDUCTION OF REIMBURSED PHARMACEUTICALS COULD RESULT IN INCREASED PHARMACEUTICAL EXPENDITURE?

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OBJECTIVE: Political objectives may alter economic rationale in health care decision-making. The Hungarian government had promised to reduce the prices and copayment of pharmaceuticals, therefore 15% price cut was mandated to all reimbursed pharmaceuticals from April 2004. Three months later the regulation was abrogated by the Constitution Court. As the government did not want to communicate a price increase, the level of copayment remained the same, while the reimbursement level was increased. It took two years to increase the copayment back to the original level by a 7.5% reimbursement reduction in February 2005, and by a further 7.5% reduction from February 2005 to July 2006. Our objective was to measure the impact of price cut on the public pharmaceutical budget. **METHODS:** An estimated public pharmaceutical spending was calculated based upon projections from the expenditure in previous periods. Only pharmaceuticals with reimbursement in April 2004 were included into the analysis. The estimated expenditure was compared to the real expenditure. Hungarian Forint was converted to US$ by employing the quarterly exchange rate. **RESULTS:** In Q2 2004 the mandated price cut resulted in $39.65 million savings in the pharmaceutical expenditure. In Q3-Q4 2004 the reduced copayment generated $29.98 million increase in the drug budget. Between Q1 2005 and Q2 2006 the impact of reduced copayment was $42.42 million. **CONCLUSION:** The mandated price cut and its subsequent abrogation resulted in $32.75 million increase in the Hungarian public pharmaceutical expediture between April 2004 and June 2006, as the government did not dare to withdraw its promise on cheaper pharmaceuticals. Our estimate is conservative, as the mandated price cut influenced spending not only on pharmaceuticals with reimbursement in April 2004, but via reference pricing also the spending on new pharmaceuticals with initial reimbursement between April 2004 and June 2006.

WITHDRAWN **PHP18**

PHP19

EFFECT OF PRESCRIPTION DRUG COVERAGE ON HEALTH AMONG CHRONICALLY ILL ELDERLY POPULATION

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OBJECTIVE: To estimate the effect of prescription drug insurance on health, as measured by self-reported poor health status, functional disability, and hospitalization among elderly with at least three chronic conditions. **METHODS:** Analyses are based on a nationally representative sample of non-institutionalized elderly (>64 years of age) from the Medicare Current Beneficiary Survey (MCBS) for years 1992–2000. Estimates are obtained using multivariable regression models that control for observed characteristics and unmeasured person-specific effects (i.e., fixed effects). Fixed effects analysis uses within person variation in drug coverage to estimate the effect of gaining or losing coverage on outcome of interest (i.e., health). **RESULTS:** In general, prescription drug insurance was not associated with significant changes in self-reported health, and hospitalization. However, prescription drug coverage decreased functional disability slightly (4% improvement), although this was not statistically significant. **CONCLUSION:** Findings suggest that prescription drug coverage may have some health benefits for chronically ill.

PHP20

PREDICTORS OF ENROLLMENT IN MEDICARE PART D: THE EXPERIENCE OF MEDICARE DRUG DEMONSTRATION PARTICIPANTS WITH RHEUMATOID ARTHRITIS AND MULTIPLE SCLEROSIS

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OBJECTIVE: During the 16 months preceding the start of the Medicare prescription drug program (Part D), 22,359 vulnerable Medicare beneficiaries with rheumatoid arthritis (RA) or multiple sclerosis (MS) participated in the Medicare Replacement Drug Demonstration (MRDD), which provided access to specialty biologic medications. We examine beneficiary characteristics associated with Part D enrollment among this population in early 2006. **METHODS:** Predictors in multivariate logistic regressions included female gender, age, race (white, black, or other), region of the U.S., urban residence, Hierarchical Condition Category score (HCC; a measure of comorbidity), use of the MRDD benefit, subsidy level under the MRDD, self-report of other drug coverage during the MRDD, and death within six months of the start of Part D. **RESULTS:** Among 14,963 MRDD beneficiaries with RA, 12,174 (81%) enrolled in Part D plans during the first half of 2006. Ninety percent (6646) of the 7396 beneficiaries with MS enrolled in a Part D plan—about 50% higher than the rate of enrollment in the general Medicare population. Female gender (OR = 1.5, 1.3–1.6), MRDD benefit use (OR = 2.6, 2.4–2.8), higher HCC score (OR = 1.07, 1.03–1.10), other drug coverage during the MRDD (OR = 1.6, 1.5–1.7), were associated with Part D enrollment. There were regional differences as well. Older age (OR = 0.9, 0.9–0.9) and death within 6 months (OR = 0.3, 0.3–0.4) were associated with not enrolling in Part D. Separate regressions for the RA and MS populations produced similar results. **CONCLUSION:** With the inception of Medicare Part D, most MRDD beneficiaries with RA and MS enrolled in Part D plans. Beneficiaries who had used their MRDD benefit and had worse health status—those who appear to need prescription drug coverage most—were more likely to enroll. Disproportionately high enrollment suggests that